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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,548	BAUER ET AL	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,31,35-38,40-45 and 47-74* is/are pending in the application.

4a) Of the above claim(s) *50-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29,31,35-38,40-45 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.D.

DETAILED ACTION

Status of the claims

The amendment filed May 19, 2005 is acknowledged and has been entered.

Election/Restrictions

1. Newly submitted claims 50-74 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 1-29, 45 and claims 50-62 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product such as a test strip in which the detectable tracer zone is located upstream of the application zone such as taught by Friesen et al (US 4,861,711) (see previous office action for Friesen et al). Further, the product as claimed can be made by another and materially differ process such as a process in which a single test strip is subjected to a printer in which the printer comprises all the necessary reagents to print the reagents on each zone.

Claims 31, 35-38, 40-44 and 47-49, and claims 50-62 are independent and distinct interventions. Claims 31, 35-38, 40-44 and 47-49 require contacting and determining steps to determine an analyte and claims 60-62 do not require these limitations.

Claims 1-29, 45 and 63-74 are independent and distinct inventions. Claims 63-74 require the primary capture area already at least partially occupied by analyte and claims 1-29, 45 and 63-74 doe not require this limitation. Further, Claim 1 requires a detectable tracer whereas claim 63 requires a detectable conjugate. Further, claims 63-74 requires the sample application area is more superficially positioned on the test strip than the conjugate and claims 1-29 and 45 do not require this limitation.

2. 31, 35-38, 40-44, 47-49 and claims 63-74 are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus such as the test strip of claim 1 or a test strip wherein the detectable tracer is located upstream of the sample application zone (see Friesen, US 4,861,711).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 50-74 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 20, lines 7-9 in the specification. The applicant discloses the sample and A-L-T conjugate may be applied substantially simultaneously to pad 230, but the sample is applied at a more distal position on strip 220. The applicant does not disclose a path of liquid flow along a bibulous substrate from the sample application area distally through the mobilization zone to the primary capture area and then to the secondary capture area, wherein the liquid sample is applied to the test strip at a position closer to the primary capture area than the detectable tracer is applied to the test strip. There is no description in the specification disclosing a path of liquid flow along a bibulous substrate from the sample application area distally through the mobilization zone to the primary capture area and then to the secondary capture area, wherein the liquid sample is applied to the test strip at a position closer to the primary capture area than the detectable tracer is applied to the test strip.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4, 6, 20, 31, 35-38, 40-44 and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 the recitation "detectable tracer is selected to interact with the test strip to slow migration" is vague and indefinite. It is unclear how the tracer interacts with the test strip. Does the tracer bind to the test strip? Does the tracer since it is larger than the analyte cause it to bump into the test strip to slow it down? Does the tracer have an attraction to the test strip? Please clarify.

Claim 6 is vague and indefinite because it contradicts independent claim 1. Claim 1 requires that the detectable tracer be in the mobilization zone which is required to be distal from the application area. Claim 6 recites "the detectable tracer is positioned beneath the surface of the test strip on which the liquid sample is placed". It is unclear how the detectable tracer is distal to the application area if it is located beneath the sample application area. For example, the specification on page 24 lines 11-13 discloses "The mobilizable analyte-tracer conjugate can be located beneath the application zone **or** distal to the application zone".

Claim 20 the recitation ""the secondary capture area is such that the quantity of detectable tracer binding to the secondary capture area, and by correlation the amount of the analyte in the liquid sample, is indicated by a detection signal of the detectable tracer in the secondary capture are". It is unclear what applicant intends. Is this referring to method steps of using the test strip? Does the test strip comprise a

predetermined amount of immobilized secondary binding partner? Does applicant intend something else? Please clarify. See also deficiency found in claim 21.

Claim 31 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim recites a method for detecting and/or quantitating an analyte but the body of the claim does not positively recite method steps for detecting and/or quantitating the analyte. It is recommended to include a detection step to detect the signal from the secondary capture area to detect and/or quantitate the analyte.

Claim 48 is vague and indefinite because it contradicts claim 31 which depends from claim 1. Claim 1 requires that the distal flow is from sample application area distally through the mobilization zone to the primary capture area and then to the secondary capture area. Claim 48 requires that he liquid sample is applied to the test strip at a position closer to the primary capture area than the detectable tracer is applied to the test strip. It is unclear how the sample area can be closer to the primary capture area than the detectable tracer if the sample area is required to be upstream of the detectable tracer as required in claim 1. Please clarify.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 3-5, 10-13, 20, , 21, 31, 35, 36, 40, 41, 45 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al (WO 98/39657).

Boehringer et al disclose a device and method for determining an analyte of interest. Boehringer et al disclose the device comprises a sample receiving zone (sample application area); a labeling zone (mobilization zone); and primary and secondary capture zone (Figure 1). Boehringer et al disclose that the labeling zone can comprise a labeled analyte analog. Boehringer et al disclose that the capture zones comprise an immobilized specific binding pair member. Boehringer et al disclose that

the analyte and labeled analyte analog (tracer molecule) compete for binding to the immobilized binding pair member. Boehringer et al also disclose that the sample flows sequentially past the capture zones (p. 16, lines 9-38). Boehringer et al disclose the flow matrix can be bibulous (p. 31). Boehringer et al disclose that the pore size of the bibulous membrane is 1 to 20 microns (1000 to 20000 nm) (p. 32). Boehringer et al disclose that the sample can be saliva (p. 7). Boehringer et al also disclose that the device and components can be packaged in the form of a kit and that the kit can also contain instructions for performing the methods and interpreting the results (p. 36, lines 1-8).

Boehringer et al differ from the instant invention in failing to specifically state that the detectable tracer molecule migrates through the device at a rate slower than a rate and that the analyte reaches the primary capture area before the tracer reaches the primary capture area.

Although Boehringer et al does not specifically state the slower rate as recited in the claims, Boehringer et al does disclose that the detectable tracer molecule can be a labeled analyte analog (p. 9). Boehringer et al disclose that the analyte analog refers to a modified analyte in which the analyte has been modified to provide a means for attaching the analyte to another molecule. Boehringer et al disclose attaching this analyte analog to BSA coated latex microspheres (p. 43-45). Since the microspheres of Boehringer et al are even larger (0.51u) than the particles disclosed in the specification on page 21 and are coated with BSA, one of ordinary skill in the art would recognize that the rate of migration for the labeled analyte analog would be slower than the rate of

migration of the analyte and thus the analyte would reach the primary capture area before the detectable tracer.

11. Claims 2, 6 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. in view of Fredrickson (US 6001,658).

See above for teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically teach the detectable tracer is positioned beneath the surface of the test strip on which the liquid sample is placed.

Frederickson teaches detectable tracer impregnated (defined in Webster's as to permeate, permeate is also defined in Webter's as to penetrate or pass through) in a mobilization zone. Therefore, Frederickson teaches that the tracer is beneath the surface of the test strip. Frederickson teaches that this provides for a rapid, volume, timing and termperature independent visually read test strip. Further, the impregnation of labeled reagents within test strips is known in the art as taught by Bogema (US 6,248,598) (col 4, lines 50-56).

It would have been obvious to one of ordinary skill in the art to impregnate the detectable tracer as taught by Frederickson into the device and methods of Boehringer et al because Frederickson teaches that this provides for a rapid, volume, timing and termperature independent visually read test strip. Further, the impregnation of labeled reagents within test strips is known in the art. Therefore, one of ordinary skill in the art would have a reasonable expectation of success impregnating the detectable tracer as taught by Frederickson into the device and methods of Boehringer et al.

12. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Leuvering (US 4,313,734).

See above for teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically state that the detectable tracer comprises a visually detectable label covalently attached to analyte or an analyte analog.

Leuvering disclose particles (detectable tracer) coupled to reactive components. Leuvering disclose that the components can be coupled to the particles by covalent bonds (col 2). Leuvering disclose that these particles carry a charge (col 3) and that the particles can be combined with other reagents. Leuvering disclose that these particles can be visually detected (col 5). Leuvering disclose that the particles can be 100 nm (size which falls within the size disclosed by Applicant on page 21 of the specification). Leuvering disclose that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific binding protein and the corresponding bindable substance in a test sample (col 1) and also proves to be more sensitive than known techniques (col 3).

It would have been obvious to one of ordinary skill in the art to incorporate labels as taught by Leuvering into the device and methods of Boehringer et al because Boehringer et al specifically teaches that labels provided in Leuvering (US 4,313,734) are suitable labels for the device and methods of Boehringer (p. 34, lines 21-37) and also because Leuvering teaches that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific

binding protein and the corresponding bindable substance in a test sample and also proves to be more sensitive than known techniques. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating the labels of Leuvering into the method and device of Boehringer et al.

With respect to claim 7 since the combination of Boehringer et al and Leuvering disclose the same device and reagents as recited in the instant claims one of ordinary skill in the art would expect the detectable tracer to have a retarded migration rate relative to the migration of the analyte.

13. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Leuvering as applied to claims 1-5, 7,10-14, 20, 31, 36, 40, 41 and 45 above, and further in view of Terminiello et al (US 4,774,192).

See above for teachings of Boehringer et al and Leuvering.

Boehringer et al and Leuvering differ from the instant invention in failing to teach the at least one reagent is polyvinyl pyrolidone.

Terminiello et al disclose the treatment of membranes used in the analysis of a fluid sample. Terminiello et al disclose treating the membrane with polyvinyl pyrolidone (PVP). Terminiello et al disclose that the purpose of such conditioning of the membrane provides the advantages of reducing the void space within the matrix of the membrane and to assist or promote the absorption of the fluid fraction of the biological sample.

It would have been obvious to one of ordinary skill in the art to treat the modified device of Boehringer et al with PVP as taught by Terminiello et al because Terminiello et al shows that such conditioning of the membrane provides the advantages of

reducing the void space within the matrix of the membrane and to assist or promote the absorption of the fluid fraction of the biological sample.

14. Claims 15, 17-19, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Fitzpatrick et al (US 5,451,504).

See above for the teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically teach the analytes.

Fitzpatrick et al disclose test strips, which will detect any antigen in which the appropriate reagents are used. Fitzpartrick et al disclose that the analyte can be drugs and small analytes of 100 to 1000 Daltons (col 4). Fitzpartrick et al disclose that detecting drugs or drug metabolites affects the choice of proper medical treatment and that the detection of drugs or drug metabolites in a person is also important in law enforcement.

It would have been obvious to one of ordinary skill in the art to detect any analyte and incorporate the appropriate reagent such as taught by Fitzpatrick into the test strip and method of Boehringer et al because Fitzpatrick et al shows that the detection of analytes affects the choice of proper medical treatment.

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Hardman et al (US 6,573,108).

See above for teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically teach the detectable tracer comprises a detectable tracer for an analyte comprising an antibody to HIV or Hepatitis.

Hardman et al teach reagents used in test strips for determining an analyte of interest. Hardman et al teaches that antibodies or antigens are used to determine the analyte of interest. Hardman et al teaches the analyte of interest can be HIV or Hepatitis antigens and that one would use antibodies specific for the antigens in testing procedures (col 5, lines 10-37). Hardman et al teaches that this provides for determining for antigens of diagnostic significance.

It would have been obvious to one of ordinary skill in the art to incorporate reagents such as taught by Hardman et al into the device and methods of Boehringer et al because Boehringer et al specifically teaches the analyte can be a virus (p. 8) and Boehringer et al is generic with respect to the virus and one of ordinary skill in the art would use the appropriate reagents to determine the analyte of interest in the case HIV. Further, Hardman teaches that these reagents provide for determining antigens of interest.

16. Claims 22 -24, 26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al (W0 98/39657) in view of Leuvering (US 4,313,734).

See above for teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically state the detectable tracer covalently coupled to analyte or an analyte analog.

Leuvering disclose particles (detectable tracer) coupled to reactive components. Leuvering disclose that the components can be coupled to the particles by covalent bonds (col 2). Leuvering discloses that the coating the particles with a macromolecule (linker) which couples to the component covalently. Leuvering disclose that the particles can be gold particles (col 3, lines 25-26). Leuvering disclose that these particles carry a charge (col 3) and that the particles can be combined with other reagents. Leuvering disclose that these particles can be visually detected (col 5). Leuvering disclose that the particles can be 100 nm (size which falls within the size disclosed by Applicant on page 21 of the specification). Leuvering disclose that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific binding protein and the corresponding bindable substance in a test sample (col 1) and also proves to be more sensitive than known techniques (col 3).

It would have been obvious to one of ordinary skill in the art to incorporate covalently coupled labels as taught by Leuvering into the device and methods of Boehringer et al because Boehringer et al specifically teaches that labels provided in Leuvering (US 4,313,734) are suitable labels for the device and methods of Boehringer (p. 34, lines 21-37) and also because Leuvering teaches that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific binding protein and the corresponding bindable substance in a test sample and also proves to be more sensitive than known techniques. Therefore, one of ordinary skill in the art would have a reasonable expectation of

success incorporating the labels of Leuvering into the method and device of Boehringer et al.

With respect to the migration rate as recited in the instant claims. Since the combination of Boehringer et al and Leuvering disclose particles attached to the analyte analog and disclose that the particles are the same size as used by the Applicant one of ordinary skill in the art would recognize that the rate of migration for the labeled analyte analog would be slower than the rate of migration of the analyte and thus the analyte would reach the primary capture area before the detectable tracer.

17. Claims 25, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Leuvering in view of Bangs Laboratories (Technote 201, Working with microspheres, 9/29/99, pages 1-16.

See above for the teachings of Boehringer et al and Leuvering.

Boehringer et al differ from the instant invention in failing to specifically stated that the detectable tracer is a latex particle covalently coupled to the analyte or analyte analog.

Bangs teaches latex particles covalently coupled to reactants. Bangs discloses numerous chemical groups, which are used as linkers to covalently couple the reactant to the microspheres. Bangs teaches that these chemical groups can comprise a carbon (pages 8-10). Bangs teaches the advantages of linkers. Bangs teaches these particles are used in assays involving test strips (pages 12-13). Bangs teaches that the covalently coupling of reactant to microspheres provides numerous advantages (pages

8-9) such as preventing desorbtion, are more thermally stable and makes it easier to control coating level and uniformity.

It would have been obvious to one of ordinary skill in the art to incorporate covalent coupling and latex beads as taught by Bangs into the modified device and methods of Boehringer et al because Boehringer et al specifically teaches that particle can be latex and Bangs teaches that the microspheres (particles) can be used in test strips and provides the advantages of preventing desorbtion, are more thermally stable and makes it easier to control coating level and uniformity. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating micropsheres and covalent coupling as taught by Bangs into the modified device and method of Boehringer et al.

18. Claims 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Thieme et al (US 5,871,905).

See above for the teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to teach the saliva is combined with a bile acid or bile salt.

Thieme et al disclose the use of saliva as a liquid sample in immunoassays involving lateral flow immunochromatographic devices (col 1). Thieme et al disclose that the saliva is combined with a bile salt or acid (col 3, lines 19-25). Thieme et al disclose that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample. Thieme et al also disclose that a chelator such as EDTA can be impregnated

into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives (col 15, lines 42-61).

It would have been obvious to one of ordinary skill in the art to incorporate a bile acid or bile salt in combination with the saliva as taught by Thieme et al into the method of Boehringer et al because Thieme et al shows that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample.

It would have also been obvious to one of ordinary skill in the art to incorporate a chelator such as taught by Thieme et al into the test strip and method of Boehringer et al because Thieme et al shows that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1-29, 31, 35-38, 40-45 and 47-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 18-20 and 25-37 of U.S. Patent No. 6,699,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the claims or U.S. Patent No. 6,699,722 would encompass the claims of 1-38 of application 10/686,548.

Response to Arguments

21. Applicant's arguments filed May 19, 2005 have been fully considered but they are not persuasive.

103 Rejections

Applicant argues that Boehringer et al. neither discloses nor suggests and arrangement in which the detectable tracer is positioned in the path of flow on the test strip in a position that a distal flow of analyte through a bibulous substrate reaches the primary capture area before a distal flow of tracer. Applicant states that although the reference does disclose a lateral flow device in which liquid flows from a sample pad to a labeling zone and barrier zone and capture zone it fails to establish a prima facie case of obviousness because it dos not disclose or suggest the claimed limitations. For example, it is not clear from the Boehringer et al reference whether a distance between the labeling zone and barrier zone is great enough to allow separation of the wave fronts of the label and analyte before they reach the barrier zone. This is not found

persuasive because the features upon which applicant relies (i.e., distance between the labeling zone and the capture zone) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant further argues that since Boehringer et al. did not even appreciate the desirability of achieving the separation, they can not be said to have disclosed or suggested the claimed solution. This is not found persuasive because the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant further argues that the Boehringer reference can not be said to disclose migration of an analyte in advance of a labeled conjugate. As shown in the attached Declaration of Robert Buck, a large conjugate and analyte can flow together to the primary capture zone is not sufficient to permit the separation of the conjugate and analyte. The declaration is not found persuasive because it is not commensurate with the scope of the claims. Nowhere in the claims is a recitation of distance between the zones. Applicant has not disclosed any structural element that is different from the prior art and thus the prior art reads on the instantly recited claims. Further, Applicant's statement that they have observed (see number 5 comment of the declaration) that covalent coupling of a tracer to an analyte or analyte analog in the claimed assay produced a more reliable assay is not found persuasive because the combination of

Boehringer et al and Leuvering teaches this limitation and thus would provide for a more reliable assay and it is noted that covalently coupling is not recited in claim 1, but is only recited in claims 14 and 22..

Applicant argues that the claimed placement of the detectable tracer on the test strip in a position that a distal flow of analyte reaches the primary capture area before a distal flow of tracer provides an expectedly superior result. Applicant states that as demonstrated in the Declaration of Robert Buck, such placement of the tracer provides greater sensitivity of test results by permitting more effective separation of the wave fronts. This is not found persuasive because as stated above the declaration is not commensurate with the scope of the claims. Nowhere in the claims is a recitation of distance between the zones. Further, Applicant has not shown why the distance of the tracer zone from the primary capture zone of the current application is better than that of Boehringer et al. Boehringer et al shows that the tracer zone is located at a distance from the primary capture area (see figure 1). Therefore, it is the Examiner position that Boehringer et al and the secondary references read on the instantly recited claims.

With respect to Applicant's arguments as directed to the covalent coupling of the tracer are moot in view of the new grounds of rejections. See above for rejections concerning covalent coupling of the tracer.

Applicant argues that claim 45 concerns a test kit containing instructions for use of the test strip such that flow of analyte in the liquid sample reaches the primary capture zone before the flow of tracer and that the prior art does not disclose or suggest this feature. This is not found persuasive because as stated above it is the Examiner's

position that the analyte reaches the primary capture area before the tracer and the prior art teaches instructions in a kit. Further, the intended use of the instructions is not relevant because this is intended use of the instructions and since the prior art teaches instructions provided in a kit, the prior art reads on the instantly recited claims.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
July 18, 2005

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SUPERVISORY PATENT EXAMINER
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07/21/05